

### **III. Remarks**

#### **A. Status of the Application**

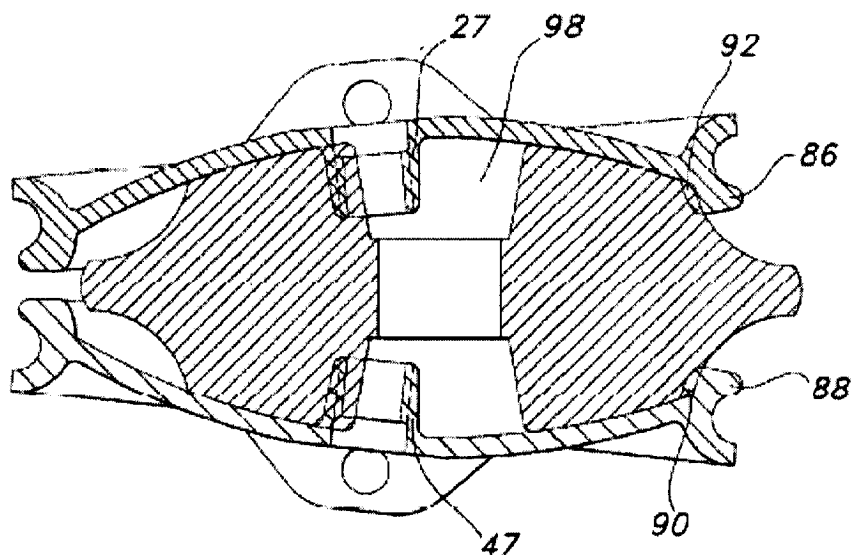
Claims 3, 10-17, 23-40, 43, 44, 56-61, 66, 67, 70, 71, 74-76, 86-96, 101-103, 106-110, 112-119, 121, and 122 are currently pending. Claims 93-96, 101-103, 106-110, 112, 113, 121, and 122 were previously withdrawn from consideration as being directed to an unelected invention. Claims 41 and 42 are canceled by the present paper without prejudice to or disclaimer of the subject matter therein. Claim 43 has been amended to be in independent form, incorporating all of the limitations of its base claims such that the scope of claim 43 is unchanged. Claims 66, 67, and 70 have been amended to depend from and further limit claim 43. No claims are added by the present paper. Applicants appreciate the indication of allowance for claims 91, 92, and 114-119. Reconsideration of the present application in light of the following remarks is respectfully requested.

#### **B. Rejections under 35 U.S.C. § 102**

##### **1. The Buttner-Janz Patent**

The Office Action indicated that **claims 56-61** are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,401,269 to Buttner-Janz et al. ("the Buttner-Janz patent"). Therefore, to sustain the rejection of the claims 56-61 the Buttner-Janz patent must disclose all of the claimed elements of each claim.

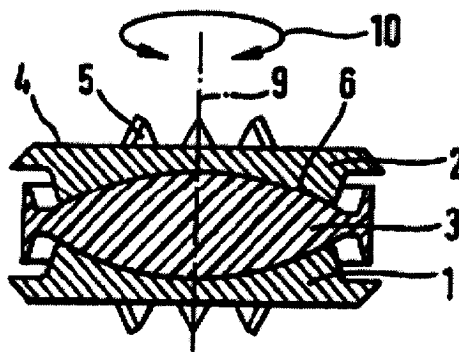
With respect to independent claim 56, the Buttner-Janz patent at least fails to disclose an implant having all of the recited features of the claim, including "wherein the central body has an upper and a lower contact surface, and wherein in the absence of a compressive load, an upper shoulder is recessed into a portion of the perimeter of the upper contact surface and a lower shoulder is recessed into a portion of the perimeter of the lower contact surface." (emphasis added). As shown below, Fig. 8B of the present application illustrates an exemplary embodiment of a central body having upper and lower shoulders 90 and 92 recessed into a portion of the perimeter of the respective contact surfaces.



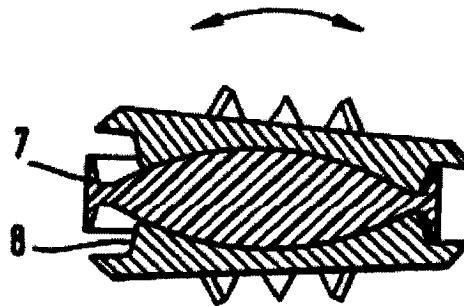
**FIG 8B**

The cited portions of the Buttner-Janz patent simply do not disclose having shoulders recessed in the upper and lower contact surfaces as recited. Rather, as shown in Figs. 1 and 2 of the Buttner-Janz patent, reproduced below, the collar 7 surrounding and defining the perimeter of the prosthesis core 3 is not recessed into the articular surfaces 6. Rather, the collar 7 projects outwardly at an increased height from the articular surfaces 6. Further, the area just inside the collar 7 having a reduced height relative to the collar cannot be considered a shoulder as recited because it is not recessed into a portion of the perimeter as required.

**Fig. 1**



**Fig. 2**



In response to this argument, the present Office Action asserts that, "As claimed by the applicant the upper and lower shoulders only have to be recessed in[t]o a portion of the perimeter. Applicant did not indicate[] where in the perimeter the shoulder must be recessed, as long as it is recessed into a portion of the perimeter." Applicants agree that there is no limitation on where in the perimeter the shoulders must be recessed. However, as claimed, the shoulders must be recessed into the perimeter or outer boundary of the device, not within the device as disclosed by the Buttner-Janz patent. In that regard, dictionary.com provides the following pertinent definitions of perimeter:

1. the border or outer boundary of a two-dimensional figure.
2. the length of such a boundary.
3. a line bounding or marking off an area.
4. the outermost limits.

It is clear that the protruding collar 7 in the Buttner-Janz patent defines the border, outer boundary, and outermost limits of the core 3. The recessed portion of the core 3 as identified by the Office Action is positioned inside the collar 7 and spaced from the perimeter or outer boundary of the core 3. Accordingly, it is clear that the core 3 of the Buttner-Janz patent does not disclose an upper shoulder recessed into a portion of the perimeter of the upper contact surface and a lower shoulder recessed into a portion of the perimeter of the lower contact surface, as recited by claim 56.

For at least this reason, the Buttner-Janz patent fails to disclose all of the limitations of independent claim 56. Claims 57 and 58 depend from and further limit claim 56. Therefore, for at least these reasons Applicants respectfully request that the §102 rejection of claims 56-58 be

withdrawn.

Similar to independent claim 56, independent claim 59 requires “wherein an upper shoulder extends around a portion of the perimeter of the upper contact surface and a lower shoulder extends around a portion of the perimeter of the lower contact surface and further wherein the upper shoulder defines a ledge indented into and around the perimeter of the upper contact surface of the central body.” As discussed above, the Buttner-Janz patent fails to disclose such limitations. Therefore, for at least the same reasons, the Buttner-Janz patent fails to disclose an implant with all of the recited limitations of claim 59. Claims 60 and 61 depend from and further limit claim 59. Therefore, Applicants respectfully request that the §102 rejection of claims 59-61 be withdrawn.

**C. Rejections under 35 U.S.C. § 103**

**1. The Fuhrmann and Ray Patents**

**Claims 74-76** stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,002,576 to Fuhrmann et al. (“the Fuhrmann patent”) in view of U.S. Patent No. 6,132,465 to Ray et al. (“the Ray patent”). Applicants respectfully traverse the rejection of claims 74-76 on the grounds that these references are defective in establishing a *prima facie* case of obviousness.

As the PTO recognizes in MPEP § 2142:

... The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness...

It is submitted that a *prima facie* case of obviousness has not been factually supported with respect to each of these claims in the present case.

With respect to independent claim 74, even when combined the Fuhrmann and Ray patents fail to disclose all of the recited features of the claim, including “at least two opposing shells, a central body disposed between the two opposing shells, and at least one sealable opening in one of the at least two opposing shells for the introduction of a lubricant into the implant between the central body and the opposing shells after the implant has been assembled.” Rather,

the opening 21 in the cover plate 3" of the Fuhrmann patent "serves to fill the interior with viscoelastic material—or, together with a similar opening, as ventilation." Col. 4, Lines 10-12. In the Fuhrmann patent, the viscoelastic material fills a closed corrugated tube 1 to create the central spring body. Col. 2, Lines 52-67. In other words, the viscoelastic material 2 is part of the central body of the Fuhrmann device. Thus, the opening 21 is not for the "introduction of a lubricant into the implant between the central body and opposing shells," as required. Rather, the opening 21 of the Fuhrmann disc is for filling the corrugated tube 1 with the viscoelastic material 2 to form the central spring body. The viscoelastic material cannot be introduced between a central body and opposing shells because **the viscoelastic material is the central body**. Similarly, the hydrogel core 22 of the Ray patent is positioned within the constraining jacket 24 of the prosthetic nucleus 20 and "is configured to imbibe fluids, expanding from a dehydrated state to a hydrated state." Col. 6, ll. 63-65. The opening of the Ray patent is not for introducing a fluid between a central body and opposing shells as required. Rather, the opening is for introducing the fluids into the hydrogel core.

In response to these arguments, the present Office Action asserts that, "applicant is not positively claiming these limitations. Applicant is only claiming that the opening is capable of introducing a lubricant." Applicants respectfully disagree. Applicant is not "only claiming that the opening is capable of introducing a lubricant," but rather Applicant is claiming that the opening facilitates "the introduction of a lubricant into the implant **between the central body and the opposing shells after the implant has been assembled**." These are structural limitations of the opening that are positively recited by the claim. In contrast and as discussed above, the openings of the Fuhrmann and Ray patents do not allow the introduction of a lubricant between a central body and opposing shells as recited by claim 74.

Accordingly, for at least these reasons, even when combined the Fuhrmann and Ray patents fail to disclose all of the recited elements of claim 74. Therefore, Applicants respectfully request that the §103 rejection of claim 74 over the Fuhrmann and Ray patents be withdrawn.

With respect to independent claim 75, even when combined the Fuhrmann and Ray patents fail to disclose all of the recited features of the claim, including "a central body and a

lubricant encapsulated within the implant between the central body and a structure having at least one opening for the introduction of the lubricant into the structure, wherein the structure includes two shells and a sleeve extending between the shells, and the opening is included in at least one of the shells.” As discussed above with respect to claim 74, the Fuhrmann and Ray patents simply do not disclose such limitations. Claim 76 depends from and further limits claim 75. Accordingly, the Applicants request that the §103 rejection of claims 75 and 76 over Fuhrmann and Ray patents be withdrawn.

## **2. The Buttner-Janz, Buechel, Fuhrmann, and Ray Patents**

**Claim 3 and 10-15** stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Buttner-Janz patent in view of U.S. Patent No. 5,868,796 to Buechel et al. (“the Buechel patent”), in view of the Fuhrmann patent, in view of the Ray patent. Applicants respectfully traverse the rejection of these claims on the grounds that these references are defective in establishing a *prima facie* case of obviousness.

Claim 3 requires, “a flexible sheath extending between edges of the opposing shells, having an inner surface that, together with the inner surfaces of the rigid shells, defines a cavity containing the central body; and a liquid lubricant, which occupies at least a portion of the cavity.” However, even when combined the Buttner-Janz, Buechel, Fuhrmann, and Ray patents fail to disclose such limitations. Specifically, the references fail to disclose a liquid lubricant occupying a cavity defined by the inner surfaces of the rigid shells and the flexible sheath that contains the central body. In that regard, the viscoelastic material of the Fuhrmann patent is the central body of the Fuhrmann disc, and is not positioned within a cavity containing a central body as required. Similarly, the fluid of the Ray patent is positioned within the hydrogel core and not within a cavity containing a central body. For at least this reason, even when combined the Buttner-Janz, Buechel, Fuhrmann, and Ray patents fail to teach all of the claimed elements of independent claim 3.

Further, there is no reason for combining the opening 21 of the Fuhrmann disc and fluid of the Ray patent with the devices of the Buttner-Janz and Buechel patents other than hindsight.

Recently, the Supreme Court ruled that the “teaching, suggestion, or motivation (TSM) test” still applies, but should be used in a more “expansive and flexible” manner. *KSR Int’l. Co. v. Teleflex Inc.*, slip opinion at 14-15 (2007). The Court stated that

**“A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.”** Id. at 14-15, emphasis added.

In the present case, the Examiner has not expressed any reason why a person of ordinary skill in art would combine the opening 21 of the Fuhrmann disc with the devices of the the Buttner-Janz patent and the Buechel patent. The Office Action states that “it would have been obvious ... to modify the device of Buttner-Janz/Buechel/Bryan et al., as taught by Fuhrmann et al., to serve to fill or ventilate the interior of the implant. However, the devices of the Butter-Janz and Buechel patents include substantially solid core or central pieces. The central pieces of the Buttner-Janz patent are not formed by filling a tube with viscoelastic material as in the Fuhrmann patent. Thus, one would not modify the devices of the Buttner-Janz and Bryan patents to fill the implant with a viscoelastic material to create a central body as in the Fuhrmann patent. Further, there is no indication why one would combine ventilation with the Buttner-Janz devices. Accordingly, the Examiner has not expressed any reason why a person of ordinary skill in art would combine the opening 21 of the Fuhrmann disc with the devices of the the Buttner-Janz patent and the Buechel patent. Thus, for at least this additional reason a *prima facie* case of obviousness has not been established with respect to independent claim 3.

Claims 10-15 depend from and further limit independent claim 3. Therefore, for at least

the same reasons these references are defective in establishing a *prima facie* case of obviousness with respect to claims 10-15. Thus, Applicants request that the §103 rejection of claims 3 and 10-15 be withdrawn.

### **3. The Buttner-Janz, Buechel, Bryan, Fuhrmann, and Ray Patents**

**Claims 16, 17, 23-40, 43, 44, 66, 67, 70, 71, and 86-90** stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Buttner-Janz patent in view of the Buechel patent, in view of U.S. Patent No. 5,764,296 to Bryan et al. ("the Bryan patent"), in view of the Fuhrmann patent, in view of the Ray patent. Applicants respectfully traverse the rejection of claims 16, 17, 23-40, 43, 44, 66, 67, 70, 71, and 86-90 on the grounds that these references are defective in establishing a *prima facie* case of obviousness.

#### **a. Claims 16 and 17**

With respect to independent claim 16, even when combined the Buttner-Janz patent, the Buechel patent, the Bryan patent, the Fuhrmann patent, and the Ray patent fail to disclose an implant having all of the recited limitations, including "wherein at least one of the rigid opposing shells further comprises a closable passage between its outer surface and its inner surface ... wherein the closable passage is configured in a manner that permits the introduction of a lubricant into the implant between the central body and the opposing shells." As discussed above with respect to claims 74 and 75, the opening 21 of the Fuhrmann disc is not for the "introduction of a lubricant into the implant between the central body and opposing shells," as required. Rather, the opening 21 of the Fuhrmann disc is for filling the corrugated tube 1 with the viscoelastic material 2 to form a central spring body. As such, the viscoelastic material cannot be introduced between a central body and opposing shells because **the viscoelastic material is the central body**. Similarly, the hydrogel core 22 of the Ray patent is positioned within the constraining jacket 24 of the prosthetic nucleus 20 and "is configured to imbibe fluids, expanding from a dehydrated state to a hydrated state." Col. 6, ll. 63-65. The opening of the Ray patent is not for introducing a fluid between a central body and opposing shells as required.



Rather, the opening is for introducing the fluids into the hydrogel core. Accordingly, even when combined the Buttner-Janz, Buechel, Bryan, Fuhrmann, and Ray patents fail to disclose the recited limitations of independent claim 16.

Further, there is no reason for combining the opening 21 of the Fuhrmann disc and fluid of the Ray patent with the devices of the Buttner-Janz, Buechel, and Bryan patents other than hindsight. Recently, the Supreme Court ruled that the “teaching, suggestion, or motivation (TSM) test” still applies, but should be used in a more “expansive and flexible” manner. *KSR Int’l. Co. v. Teleflex Inc.*, slip opinion at 14-15 (2007). The Court stated that

**“A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.”** *Id.* at 14-15, emphasis added.

In the present case, the Examiner has not expressed any reason why a person of ordinary skill in art would combine the opening 21 of the Fuhrmann disc with the devices of the the Buttner-Janz patent and the Bryan patent. The Office Action states that “it would have been obvious ... to modify the device of Buttner-Janz/Buechel/Bryan et al., as taught by Fuhrmann et al., to serve to fill or ventilate the interior of the implant. However, the devices of the Butter-Janz and Bryan patents include substantially solid core or central pieces. The central pieces of the Buttner-Janz and Bryan patents are not formed by filling a tube with viscoelastic material as in the Fuhrmann patent. Thus, one would not modify the devices of the Buttner-Janz and Bryan patents to fill the implant with a viscoelastic material to create a central body as in the Fuhrmann patent. Further, there is no indication why one would combine ventilation with the Buttner-Janz and Bryan

devices. Accordingly, the Examiner has not expressed any reason why a person of ordinary skill in art would combine the opening 21 of the Fuhrmann disc with the devices of the the Buttner-Janz patent and the Bryan patent.

For at least these reasons, a *prima facie* case of obviousness has not been established with respect to claim 16. Claim 17 depends from and further limits claim 16. Therefore, Applicants respectfully request that the §103 rejection of claims 16 and 17 be withdrawn.

#### **b. Claims 23-40**

With respect to independent claim 23, even when combined the Buttner-Janz patent, the Buechel patent, the Bryan patent, the Fuhrmann patent, and the Ray patent fail to disclose an implant having all of the recited limitations, including “an elastic sheath disposed between the upper and lower shells and external to the central body, comprising an inner surface, an outer surface, an upper edge attached to the upper shell, and a lower edge attached to the lower shell; wherein the inner surface of the sheath and the inner surfaces of the shells define an enclosed cavity; and a lubricant disposed within the enclosed cavity.” Even when combined these references fail to disclose an implant with a lubricant disposed within an enclosed cavity defined by the inner surface of a sheath and the inner surfaces of the shells with a central body positioned therein. As discussed above, the viscoelastic material of the Fuhrmann patent is the central body of the Fuhrmann disc and the fluid of the Ray patent is positioned within the hydrogel core. Also, as discussed above with respect to claim 16, no reason—other than hindsight based on the present invention—has been expressed why a person of ordinary skill in the art would combine the references as suggested. For at least these reasons a *prima facie* case of obviousness has not been established with respect to independent claim 23. Claims 24-40 depend from and further limit claim 23. Therefore, for at least the same reasons these references are defective in establishing a *prima facie* case of obviousness with respect to claims 24-40.

Thus, Applicants request that the §103 rejection of claims 23-40 over the Buttner-Janz, Buechel, Bryan, Fuhrmann, and Ray patents be withdrawn.

**c. Claims 43, 44, 66, 67, 70, and 71**

With respect to independent claim 43, even when combined the Buttner-Janz patent, the Buechel patent, the Bryan patent, the Fuhrmann patent, and the Ray patent fail to disclose an implant having all of the recited limitations, including

“an upper and a lower rigid, opposed biocompatible concavo-convex shell, each comprising: ... a first ridge circumscribing the contact area of the inner concave surface and extending axially toward the opposing shell; ... a deformable, resilient central body disposed between the inner, smooth concave surfaces of the upper and lower shells, comprising: ... a shoulder circumscribing each of the smooth convex upper and lower surfaces and adapted to contact the first ridge of the adjacent shell and limit the relative motion of the shell with respect to the central body; a laterally extending equatorial ridge disposed between the first ridge of the upper concavo-convex shell and the first ridge of the lower concavo-convex shell; a plug of biocompatible material disposed in the closable passages between the outer surface and inner surface of at least one of the concavo-convex shells; and a lubricant disposed within the implant cavity.”

In particular, the cited references do not disclose a central body having a shoulder circumscribing upper and lower surfaces for contacting the ridge of a shell—the ridge circumscribing a contact area of the inner surface of the shell—and a laterally extending equatorial ridge disposed between the ridge of the upper shell and the ridge of the lower shell with a lubricant disposed within the implant cavity, as required. For at least these reasons, a *prima facie* case of obviousness has not been established with respect to claim 43. Claims 44, 66, 67, 70, and 71 depend from and further limit claim 43. Therefore, Applicants respectfully request that the §103 rejection of claims 43, 44, 66, 67, 70, and 71 over the Buttner-Janz, Buechel, Bryan, Fuhrmann, and Ray patents be withdrawn.

**d. Claims 86, 87, and 90**

With respect to independent claim 86, even when combined the Buttner-Janz patent, the Buechel patent, the Bryan patent, the Fuhrmann patent, and the Ray patent fail to disclose an implant having all of the recited limitations, including “two shells interconnected by a sleeve to

form a cavity therein, and a central body having at least one indentation therein positioned within the cavity, wherein ... at least one of the shells includes an opening to allow introduction of a lubricant into the cavity.” These references fail to disclose an implant with an opening to allow the introduction of a lubricant into a cavity defined by two shells and a sleeve with a central body positioned in the cavity, as recited. Again, the viscoelastic material of the Fuhrmann patent is the central body of the Fuhrmann disc. Further, as discussed above with respect to claim 16, no reason—other than hindsight based on the present invention—has been expressed why a person of ordinary skill in the art would combine the references as suggested. For at least these reasons a *prima facie* case of obviousness has not been established with respect to independent claim 86.

Claims 87 and 90 depend from and further limit claim 86. With respect to claim 90, even when combined the Buttner-Janz patent, the Buechel patent, the Bryan patent, and the Fuhrmann patent fail to disclose a method having all of the recited steps, including “[a] method of introducing the lubricant into the implant of claim 86 comprising slightly compressing the implant to remove excess air, and injecting the lubricant into the opening.” In particular, none of the references discloses “slightly compressing the implant to remove excess air, and injecting the lubricant into the opening,” as recited. Further, the present Office Action still makes no mention of how or what portions of the references may be interpreted to include such limitations. The provisions of 37 C.F.R. §1.104 specify that an Office Action must identify the relevant portions of a reference used to reject claims under §103. Specifically, §1.104 states, “[w]hen a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable.” The present Office Action does not reference a figure, a passage of text, or a reference numeral that would indicate which of the several embodiments of each of the references the Examiner deems to disclose the recited elements. Therefore, for at least these additional reasons a *prima facie* case of obviousness has not been established with respect to claim 90.

Thus, Applicants respectfully request that the §103 rejection of claims 86, 87, and 90 be withdrawn.

**e. Claims 88 and 89**

With respect to independent claim 88, even when combined the Buttner-Janz, Buechel, Bryan, Fuhrmann, and Ray patents fail to disclose an implant having all of the recited features, including “two shells interconnected by a sleeve to form a cavity therein, and a central body having at least one indentation therein positioned within the cavity, wherein at least one of the shells includes a retaining post that extends into the indentation and at least one of the shells includes an opening to allow introduction of a lubricant into the cavity, wherein the opening is adapted to being sealed with a plug tool having a handle and a detachable integral plug associated therewith.” Again, the opening 21 of the Fuhrmann disc is not configured for the introduction of a lubricant into cavity having a central body positioned therein. Rather, the opening 21 of the Fuhrmann disc is for filling the corrugated tube 1 with the viscoelastic material 2 to form the central body. Accordingly, the opening of the Fuhrmann patent cannot meet the recited structural limitations of claim 88. Further, as discussed above, there is no reason for combining the references as suggested other than hindsight. For at least these reasons, a *prima facie* case of obviousness has not been established with respect to claim 86. Claim 89 depends from and further limits claim 88. Therefore, Applicants respectfully request that the §103 rejection of claims 88 and 89 be withdrawn.

#### IV. Conclusion

It is believed that all matters set forth in the Office Action have been addressed and that all of the pending claims under consideration are in condition for allowance. Should the Examiner deem that an interview with Applicants' undersigned attorney would expedite consideration, the Examiner is invited to call the undersigned attorney at the telephone number indicated below.

Respectfully submitted,



Gregory P. Webb  
Registration No. 59,859

Date: 3-13-08  
HAYNES AND BOONE, LLP  
Customer No. 46333  
Telephone: 972/739-8641  
Facsimile: 214/200-0853  
File: 31132.70 / PC877.07  
R-191411\_1.DOC

**Certificate of Service**

I hereby certify that this correspondence is being filed  
with the U.S. Patent and Trademark Office via EFS-  
Web on 3-14-08.

